Message

From: Bloomberg BNA [bloomberglaw@bna.com]
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Subject: Aug. 01 -- EHS Federal Regulatory Alert

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Bloomberg Environment

EHS Federal Regulatory Alert

August 01, 2019 - Number 148

Summaries

AIR
Oklahoma SIP
AIR

Final rule of the EPA approves revisions to the Oklahoma SIP to incorporate updates to federal standards for 2013 through 2016. The revisions address requirements regarding open burning, incinerators, visible emissions and particulates, control of emission of sulfur compounds, and the primary and secondary ozone NAAQS. The agency will address revisions concerning commercial and industrial solid waste incineration units in a separate action. The rule is effective Sept. 3, 2019. Contact: Alan Shar; EPA Region 6, SO2 and Regional Haze Section; 214-665-6691; shar.alan@epa.gov. Citations: 40 CFR 52.1920

84 FR 37579 (08/01/2019)

Regulatory Update

AIR
Virginia SIP/2008 Ozone NAAQS
AIR

Proposed rule of the EPA would approve revisions to the Virginia SIP that address reasonably available control technology (RACT) requirements under the 2008 ozone NAAQS for three facilities in Northern Virginia. The revisions address nitrogen oxide

and/or volatile organic compounds RACT for Virginia Electric and Power Co.'s Possum Point Power Station and Covanta Fairfax Inc. and Covanta Alexandria/Arlington Inc.'s municipal waste combustors. Comments are due Sept. 3, 2019. Contact: Emlyn Velez-Rosa; EPA Region 3, Air and Radiation Division; 215-814-2038; velez-rosa.emlyn@epa.gov. Citations: 40 CFR 52

84 FR 37607 (08/01/2019)

Regulatory Update

ENDANGERED SPECIES

Alaska/Cook Inlet Marine Mammals Incidental Take

ENDANGERED SPECIES

Final rule of the U.S. Fish and Wildlife Service authorizes the nonlethal, incidental take by harassment of small numbers of endangered northern sea otters during oil and gas exploration, development, production, and transportation activities in Cook Inlet, Alaska, and adjacent rivers, estuaries, and coastal lands. The rule, which is in response to a request from Hilcorp Alaska LLC, Harvest Alaska LLC, and Alaska Gasline Development Corp., of Anchorage, allows incidental take for up to five years and sets forth permissible methods of taking, means for causing the least practicable adverse impact on the species, and monitoring and reporting requirements. The rule is effective Aug. 1, 2019, and expires Aug. 1, 2024. Contact: Christopher Putnam; FWS, Alaska Region Marine Mammals Management Office; 800-362-5148; fw7_ak_marine_mammals@fws.gov. Citations: 50 CFR 18.130 through 18.141 (Subpart K)

84 FR 2 (08/01/2019)

Regulatory Update

ENDANGERED SPECIES

Importation of Yellowfin Tuna from the Eastern Tropical Pacific Ocean

ENDANGERED SPECIES

Notice of the National Marine Fisheries Service announces a one-year renewal of affirmative findings for the Governments of Ecuador, El Salvador, Guatemala, Mexico, Peru, and Spain to allow the continued importation of yellowfin tuna and yellowfin tuna products from the nations, under the Marine Mammal Protection Act. The affirmative findings would apply to yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean by purse seine vessels operated under the nations'

jurisdiction or exported from the nations, in compliance with the Agreement on the International Dolphin Conservation Program. The renewal is effective April 1, 2019, and expires March 31, 2020. Contact: Justin Greenman; NMFS, West Coast Region; 562-980-3264; justin.greenman@noaa.gov

84 FR 37628 (08/01/2019)

Regulatory Update

ENDANGERED SPECIES

Importation of Yellowfin Tuna from the Eastern Tropical Pacific Ocean

ENDANGERED SPECIES

Notice of the National Marine Fisheries Service announces the issuance of a five-year affirmative finding for the Government of Colombia to allow the continued importation of yellowfin tuna and yellowfin tuna products from the nation, under the Marine Mammal Protection Act. The affirmative finding would apply to yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean by purse seine vessels operated under the Colombian jurisdiction or exported from Colombia, in compliance with the Agreement on the International Dolphin Conservation Program. The renewal is effective April 1, 2019, and expires March 31, 2024. Contact: Justin Greenman; NMFS, West Coast Region; 562-980-3264; justin.greenman@noaa.gov

84 FR 37629 (08/01/2019)

Regulatory Update

FOOD SAFETY

Color Additive Petition/Soy Leghemoglobin

FOOD SAFETY

Final rule of the FDA amends color additive standards to provide for the safe use of soy leghemoglobin as a color additive in plant-based, nonanimal derived ground beef analogue products. The rule is issued in response to a petition from Exponent Inc. on behalf of Impossible Foods Inc., of Redwood City, Calif. The FDA has determined that batch certification of soy leghemoglobin is not necessary to protect the public health. The rule is effective Sept. 4, 2019. Objections and hearing requests are due Sept. 3, 2019. Contact: Ellen Anderson; FDA, Center for Food Safety and Applied Nutrition; 240-402-1309. Citations: 21 CFR 73.520

84 FR 37573 (08/01/2019)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Developing Drugs to Treat Uncomplicated Urinary Tract Infections
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a final guidance for industry concerning the development of new drugs for the treatment of uncomplicated urinary tract infections. The guidance defines enrollment criteria for uncomplicated urinary tract infection trials, provides options for clinical trials designed to demonstrate efficacy, and describes the justification for the noninferiority margin to be used for the option of active-controlled trials designed to demonstrate noninferiority. The guidance updates the recommendations in a 1998 draft guidance that was withdrawn in an Aug. 7, 2013, notice (78 FR 48175). Comments may be submitted at any time. Contact: Joseph Toerner; FDA, Center for Drug Evaluation and Research; 301-796-1400

84 FR 37652 (08/01/2019)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Development of Drugs for Bacterial Vaginosis
GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces the availability of a final guidance for industry regarding the development of drugs for treatment of bacterial vaginosis (BV). The guidance defines enrollment criteria for BV trials and recommends that such trials be superiority trials. The guidance also reflects developments in scientific information regarding the characterization and timing of the primary efficacy endpoint. Comments may be submitted at any time. Contact: Edward Weinstein; FDA, Center for Drug Evaluation and Research; 240-402-3767

84 FR 37651 (08/01/2019)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

General Considerations for Clinical Studies
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft guidance for industry regarding general considerations for clinical studies. The guidance, which was prepared by the International Council for Harmonisation, provides an overview of the types of clinical studies of drug and biologic products and describes internationally accepted principles and practices for clinical studies of such products. The guidance also addresses identifying factors that are critical to the quality of clinical studies to promote the protection of study subjects and ways to generate reliable results while promoting efficiency of studies. Comments are due Sept. 30, 2019. Contact: Mark Levenson; FDA, Center for Drug Evaluation and Research; 301-796-2097

84 FR 37649 (08/01/2019)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Neonatal Studies for Drugs and Biological Products
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft guidance for industry concerning general clinical pharmacology considerations for neonatal studies for drugs and biological products. The guidance is intended to assist sponsors of new drug applications, biological license applications for therapeutic biologics, and supplements who are planning to conduct clinical studies in neonatal populations. The guidance is issued in response to the FDA Reauthorization Act of 2017 and supplements a 2014 guidance on pediatric drugs and biological products. Comments are due Oct. 30, 2019. Contact: Rajnikanth Madabushi; FDA, Center for Drug Evaluation and Research; 301-796-1537

84 FR 37653 (08/01/2019)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Pathology Peer Review in Nonclinical Toxicology Studies
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft guidance for industry regarding the management and conduct of pathology peer review performed during good

laboratory practice-compliant toxicology studies. The draft guidance advises the use of good laboratory practices, which includes general requirements for histopathology evaluation, and documentation practices. Comments are due Sept. 30, 2019. Contact: Tahseen Mirza, FDA, Center for Drug Evaluation and Research; 301-796-7645. Citations: 21 CFR 58

84 FR 37646 (08/01/2019)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Treatment of Uncomplicated Vulvovaginal Candidiasis
GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces the availability of a final guidance for industry to assist sponsors in the clinical development of drugs for the treatment of uncomplicated vulvovaginal candidiasis (VVC). The guidance defines enrollment criteria for VVC trials and recommends that such trials be superiority trials against placebo or active control. The guidance also reflects recent developments in scientific information concerning drugs being developed for the treatment of VVC. Comments may be submitted at any time. Contact: Shrimant Mishra; FDA, Center for Drug Evaluation and Research; 301-796-2301

84 FR 37648 (08/01/2019)

Regulatory Update

MINING
Petition for Modification of Mine Safety Standards
MINING

Notice of the Mine Safety and Health Administration announces the receipt of a petition from Rockwell Mining LLC, of Charleston, W.Va., for the modification of the application of certain existing mandatory safety standards for the Matewan tunnel mine in Boone County, W.Va. The petitioner requests modification to the part 14 belt standard. Comments are due Sept. 3, 2019. Contact: Sheila McConnell; MSHA, Office of Standards, Regulations, and Variances; 202-693-9447; mcconnell.sheila.a@dol.gov. Citations: 30 CFR 75.1108

84 FR 37682 (08/01/2019)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH
Energy Employees Occupational Illness Compensation Program
OCCUPATIONAL SAFETY AND HEALTH

Interim final rule of the Centers for Disease Control and Prevention revises standards for the Energy Employees Occupational Illness Compensation Program. The rule updates references to the International Classification of Disease (ICD) codes from ICD-9-CM to ICD-10-CM and removes outdated references to chronic lymphocytic leukemia. The rule is effective Aug. 1, 2019. Comments are due Sept. 30, 2019. Contact: Rachel Weiss; National Institute for Occupational Safety and Health; 855-818-1629; NIOSHregs@cdc.gov. Citations: 42 CFR 81.4, 81.5, 81.21, 81.23, 81.24, 81.25

84 FR 37587 (08/01/2019)

Regulatory Update

TOXIC SUBSTANCES
Identification of Explosive Materials
TOXIC SUBSTANCES

Notice announces the intention of the Bureau of Alcohol, Tobacco, Firearms and Explosives to seek OMB approval for a revised information collection request regarding the identification of explosive materials. The collection addresses requirements for manufacturers and importers of explosive materials to place specified marks of identification on such materials. The revision is due to a reduction in the number of responses, response, and public burden hours. Comments are due Sept. 30, 2019. Contact: Anita Scheddel; ATF, Explosives Industry Programs Branch; 202-648-7158; eipbinformationcollection@atf.gov. Citations: 27 CFR 555.109

84 FR 37677 (08/01/2019)

Regulatory Update

TOXIC SUBSTANCES
Importation of Firearms, Ammunition, and Implements of War/Applications and Permits
TOXIC SUBSTANCES

Notice announces the intention of the Bureau of Alcohol, Tobacco, Firearms, and Explosives to seek OMB approval for a revised information collection request concerning the application and permit for the importation of firearms, ammunition, and defense articles. The collection is used to determine if the articles described in the application qualify for importation by the importer and to serve as the authorization for the importer. Comments are due Sept. 30, 2019. Contact: Desiree Dickinson; ATF; Firearms and Explosives Imports Branch; 304-616-4584; desiree.dickinson@atf.gov

84 FR 37678 (08/01/2019)

Regulatory Update

TOXIC SUBSTANCES
Interstate Firearms Shipment Report of Theft/Loss
TOXIC SUBSTANCES

Notice announces the intention of the Bureau of Alcohol, Tobacco, Firearms and Explosives to seek OMB approval for a revised information collection request regarding Form ATF F 3310.6, which is used by licensees to report within 48 hours of discovery the theft or loss of any firearm that was in interstate transit. The revisions reflect an increased adjustment in burden. Comments are due Sept. 30, 2019. Contact: Neil Troppman; ATF National Tracing Center; 304-260-3643; neil.troppman@atf.gov. Citations: 27 CFR 478

84 FR 37677 (08/01/2019)

Regulatory Update

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